REMARKS

In the Official Action mailed June 18, 2008, the Examiner issued a Restriction Requirement and has restricted the claims in the application into four groups, which are:

Group I: claims 27, 29, 39, 40, 43, 45, 55 and 56, drawn to the particulars regarding the deposit;

Group II: claims 28, 30, 41, 44, 46 and 57, drawn to the particulars regarding the polymer substrate;

Group III: claims 31 and 47, drawn to the particulars regarding the absence of a solvent; and

Group IV: claims 34-36, 38, 50, 51, 52 and 54, drawn to the particulars regarding the plasticizing fluid/conditions.

Applicants elect Group I with traverse. Applicants also elect species (i) fluid phase deposition for Group I.

The Examiner states that the specific technical feature linking the four inventions is the process for preparation of a polymer composite comprising internally distributed deposition matter of claim 25, and that claim 25 does not provide a contribution over the prior art, represented by "Liquid State Activation" Biorise Technology Platform, XP002142912 (reference D3 from Applicants'

IPRP)(hereinafter "Biorise"). Therefore, the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicants respectfully traverse the Examiner's restriction and characterization of Biorise.

At the outset, Applicants wish to point out that no lack of unity of invention was found in the parent PCT application (PCT/GB03/01015).

Section 806.02 of the MPEP states, "For the purpose of a decision on the question of restriction, and for this purpose only, *the claims are ordinarily assumed to be in proper form and patentable (novel and unobvious) over the prior art*" (emphasis added). Applicant contends that the Examiner is taking patentability into account when reviewing the groups of inventions under PCT Rule 13.1. This is improper. The Examiner must assume that the polymer process claimed in claim 25 is patentable for purposes of the restriction requirement. Applicants respectfully request withdrawal of this restriction requirement.

Notwithstanding Applicants' contention that the outstanding restriction requirement is improper, the present invention is novel in view of the teaching in Biorise.

Applicants submit that Biorise teaches a process wherein:

a) a polymer is contacted with a solution of an active ingredient in an organic solvent; and

b) in the presence of the organic solvent, the resulting mixture is contacted with a compressed (super critical state) fluid.

The Biorise process uses the compressed fluid to displace the organic solvent and precipitate the active ingredient, resulting in the amorphous active ingredient in the polymer (carrier) (See Attachment A).

In contrast, in Applicants' process, the deposition matter of interest is mixed with a solvent that will dissolve the deposition matter, but will not dissolve the polymer being used. The resulting solution is then mixed with dry polymer particles, made by either grinding solid polymer, or spray drying a solution of polymer. The mixture of polymer and solution is then dried (the solvent is evaporated, for example, by freeze-drying). The supercritical fluid, for example, CO_2 at high pressure and 35°C, is then contacted with the dried mixture, which plasticizes the polymer, and incorporates and distributes the deposition matter within the polymer. The CO_2 is then removed. See Examples 1-4 of the specification.

In view of the foregoing, Applicants submit that one of ordinary skill in the art would understand that the Biorise process does not teach Applicants' claimed process because it does not perform the same steps in the same manner, and as such, the Biorise process cannot anticipate

claim 25 of Applicants' application. Hence, claim 25 does represent a special technical feature linking all the pending claims, and Applicants respectfully request withdrawal of the Restriction Requirement.

It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for examination and allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,
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ATTACHMENT A

Biorise®

Eurand's novel Biorise® technology is fully validated and commercialized and can be applied to a wide range of compounds to enhance bioavailability and solubility.

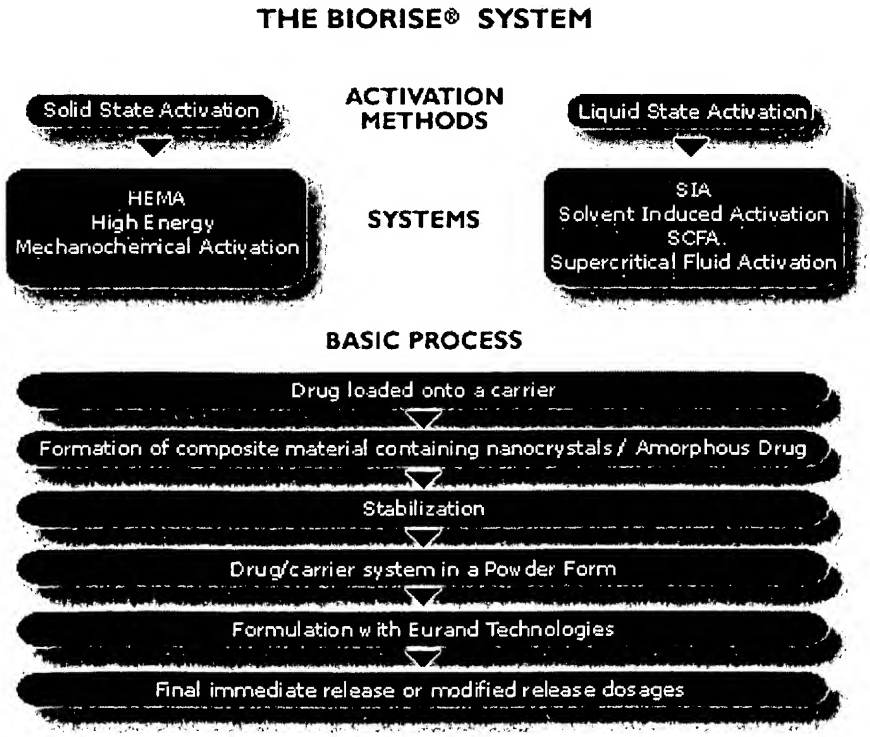
Biorise can provide additional benefits including accelerated onset of action, lower dose levels, improved market acceptability and the development of oral dosage forms that might not otherwise be possible.

To learn more about the benefits of Biorise, click on the following:

- Mesulid Fast®
- Proprietary Program

How it Works

Biorise is based on the fact that the solubility of nanocrystalline and amorphous forms of drugs is higher than that of unmodified or even micronized forms. Therefore, if drug permeability is sufficient, the absorption rate and absolute bioavailability of a drug can be increased by enhancing solubility and solubilization.



Biorise creates New Physical Entities (NPEs) by physically breaking down a drug's crystal

lattice. This results in drug nanocrystals and/or amorphous drug, which are then stabilized with biologically inert carriers. The carriers used in the Biorise system are biocompatible and readily disperse in the body's GI fluids. The final product is a free-flowing powder that can be incorporated into a variety of dosage forms to achieve the most effective delivery.

Eurand uses three types of carriers; swellable microparticles, composite swellable microparticles or cyclodextrins. When used in the Biorise system, all three carrier types improve both solubility and dissolution rate as well as the rate and overall percentage of drug absorption. The selection of the appropriate type of Biorise carrier is a critical step in the process and is dependant upon the drug delivery objective, drug carrier compatibility and its drug loading capacity.

Eurand has developed a number of activation systems that can convert a drug into its thermodynamically activated state. These systems provide flexibility and allow the technology to be applied to a range of compounds with differing characteristics. These systems include:

- High Energy Mechanochemical Activation (HEMA) – This system involves the application of friction and impact energy to the drug thereby increasing its entropy and transforming the drug into its activated state. This system is a dry system and maintains the drug/carrier matrix in a powder form at all times.

- Solvent Induced Activation (SIA) – This system is particularly suitable for thermolabile compounds and compounds with a low melting point. With this system, a drug can be solubilized in an appropriate solvent and layered onto swellable, crosslinked carriers. Controlled evaporation of the solvent and drying the material creates nanoparticles and/or amorphous drug that is stabilized in a carrier.

- Super Critical Fluid Activation (SCFA) – A drug and carrier are placed in a solvent system within a soluble environment. The solvent is removed by controlled displacement using super critical fluids resulting in the precipitation of nanocrystalline and/or amorphous drug that is stabilized in a carrier.

Before Eurand begins working on a compound, our experienced teams of scientists evaluate the compound and apply a mathematical model to predict the impact that Biorise will have on a drug. This model simulates an in-vitro release profile and also determines the most appropriate carrier system as well as drug to carrier ratios. Modeling is a key component in the Biorise process as it helps to:

- Expedite development programs and accelerate the time to market
- Reduce the need for experimentation
- Speed up the rational screening process
- Rapidly predict the outcome of the project

Advantages Over Other Methods

Eurand's Biorise system can be used to improve a product already on the market, a drug currently in development as well as to rescue a drug that has been shelved due to solubility difficulties. The system also offers faster and more efficient processing times compared to other marketed technologies and is currently one of the few bioavailability enhancement technologies that is commercialized and being used in a marketed product.

The Biorise system offers additional advantages including:

- No use of surfactants
- Produces a drug powder which can be incorporated into a variety of dosage forms including tablets and capsules
- Stable
- Cost effective process
- Scaled-up, validated, approved by a regulatory agency and commercialized
- Ability to control and vary the ratio of nanocrystal and amorphous drug
- Uses GRAS materials

For more information on Biorise, please contact us at partners@eurand.com